

Message Text

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62

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 ISO-00 OES-05 EB-07 COME-00

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DRAFTED BY:DHEW/FDA JRWEINROTH MD

APPROVED BY:OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EA/ROC:KJWEAVER(INFO)

ARA/NSC-IG:RJBLOOMFIELD(INFO)

EUR/NSC-IG:JROUSE(INFO)

EA/RA:RMARTENS(INFO)

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R 241528Z APR 75

FM SECSTATE WASHDC

TO AMEMBASSY SANTIAGO

AMEMBASSY TAIPEI

AMEMBASSY BOGOTA

AMEMBASSY ATHENS

AMEMBASSY ROME

AMEMBASSY SEOUL

AMEMBASSY MEXICO

AMEMBASSY MANILA

AMEMBASSY MADRID

AMCONSUL HONG KONG

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, CI, TW, CO, GR, HK, IT, KS, MX, RP, SP.

SUBJECT: FDA ADVISORY-DEFECTIVE ANESTHESIA MACHINE

1. FDA ADVISES THAT THE HEIDBRINK SERIES DM5000 CABINET KINET-O-METER ANESTHESIA MACHINE MANUFACTURED BY OHIO MEDICAL PRODUCTS, A DIVISION OF AIRCO, INC., 3030 AIRCO DRIVE, MADISON, WISCONSIN 53701, HAVE AN INHERENT DEFECT WHICH PRESENTS A POTENTIAL HAZARD FOR INJURY. THIS ADVISORY AFFECTS ALL SUCH DEVICES WITH THE MODEL NUMBER WITH THE DM5000 SERIES MANUFACTURED BETWEEN 1968
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AND APRIL 25, 1974. THE MODEL NUMBERS RANGE BETWEEN 5000 AND 5999,

THE VARIATION BEING DUE TO ACCESSORIES ON THE DEVICE.

2. THE INHERENT DEFECT IS THAT IF A DM5000 ANESTHESIA MACHINE IS IN USE WITH A VAPORIZER VALVE OPEN AND AN OXYGEN FLUSING PROCEDURE IS USED, THE FLUSING WILL DELIVER AN UNWANTED AMOUNT OF ANESTHESIA VAPOR TO THE PATIENT. IN A LETTER DATED APRIL 25, 1974, OHIO MEDICAL INSTRUCTED THEIR FIELD REPRESENTATIVES TO ADD A SELF-ADHESIVE LABEL TO ALL DEVICES. THE LABEL READS AS FOLLOWS: "WARNING: CLOSE ALL VAPORIZER SHUT-OFF VALVES ON TOP OF THE MACHINE BEFORE FLUSHING. FLUSHING WILL DELIVER UNWANTED ANESTHESIA VAPOR IF VALVES ARE LEFT OPEN."

3. POSTS ARE REQUESTED TO DETERMINE IF CONSIGNEES HAVE RECIVED WARNING LABELS WHICH ARE TO BE ATTACHED TO UNITS THEY MAY HAVE DISTRIBUTED.

4. FOREIGN CONSIGNEES AS FOLLOWS:

INDUSTRIA CHILENA DE SOLDADUROS S.A. CASTILLA 13805, SANTIAGO, CHILE

SHENG TUNG DEVELOPMENT CO., P.O. BOX 451 TAIPEI, TAIWAN, REP. OF CHINA

TECNICA ELECTRO-MEDICA, APARTADO AEREO 3752, CARRERE 9A NO. 16-51 MEXNANINE NO. 2, BOGATA, COLUMBIA
DM. A. GAVALAS, 2 GLADSTONE STREET, ATHENS, GREECE

CORALMA S. A. S. CORSO ANDREA, PODESTA 11-1, GENOA, ITALY 16128

ASIA SCIENCE AND CO. 8. P. O. BOX 1250, 24-23, I-KA, CHOONGMOO-RO CHOONG - KU, SEOUL, KOREA

REPRESENTACIONES MEDIICO TECHEMICALS S.A. PETROLEOS MEXICANOS

TWO ADDRESSES: MAZATLAN NUMBER 83 MEXICO 11, D.F. AND AVENIDA MARIA VACIONAL NO. 329 APTLOS 53-142, 53-145 MEXICO 17, D.F.

BENQUET CONSOLIDATED, INC. MANILA, REP. OF PHILIPPINES

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GUIDO RAYOS ALVAREZ QUINTERO NO. 2 MADRID 4, SPAIN
THE VITA COMPANY P.O. BOX 1184, 40-41 CONNAUGHT RD. WEST (9TH FL.)
HONG KONG, CHINA. END
KISSINGER

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Message Attributes

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Capture Date: 01 JAN 1994
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Draft Date: 24 APR 1975
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Decaption Note:
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Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Unique ID: 00
Drafter: DHEW/FDA JRWEINROTH MD
Enclosure: n/a
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Margaret P. Grafeld
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05 JUL 2006

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TAGS: OGEN, ETRD, TBIO, CI, TW, CO, GR, HK, IT, KS, MX, RP, SP, US, FDA
To: SANTIAGO MULTIPLE
Type: TE
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